# Chairman Dingell, Subcommittee on Health hearing entitled "Reauthorization of the Medical Device User Fee and Modernization Act"

Statement of Rep. John D. Dingell, Chairman

Committee on Energy and Commerce

SUBCOMMITTEE ON HEALTH

HEARING ENTITLED “REAUTHORIZATION OF THE MEDICAL DEVICE USER FEE AND MODERNIZATION ACT”
May 16, 2007

Mr. Chairman, thank you for holding this hearing today. We are here to discuss the reauthorization of a very important piece of legislation, the Medical Device User Fee and Modernization Act, also known as “MDUFMA.” Originally passed in 2002, this program provides valuable resources to the Food and Drug Administration (FDA) to allow timely approval of safe and effective new medical devices. Additionally, MDUFMA includes important provisions that address standards for the reuse of single-use devices; that allow third-party inspections; that provide incentives for the industry to study the application of their devices on children; and that include a number of additional regulatory reforms.

While MDUFMA has worked well, we have twice made adjustments to the program through the 2004 Medical Devices Technical Corrections Act and the Medical Device User Fee Stabilization Act of 2005 to ensure its effectiveness and sustainability. Under current law, FDA’s authority to collect medical device user fees expires on October 1, 2007.

FDA’s proposal to reauthorize the medical device user fee program includes a variety of provisions that Congress will need to study. New fees would be established to provide sustainability and a sense of predictability; fees paid by small businesses would be further reduced; the third-party inspection program would be changed; performance goals would be shifted; and new innovative diagnostic tests would be developed.

In addition to these proposed device program changes, we must also discuss the issue of device safety. According to the Wall Street Journal, an internal report by FDA critiqued the agency’s practices to ensure the safety of medical devices, such as defibrillators and pacemakers. The agency concluded that the monitoring system at the Center for

Devices and Radiological Health lacked quality information on approved devices. At the same time, the agency concluded that the volume of information received exceeded the center's ability to consistently enter or review data in a routine matter. While the medical device user fee program was created to improve timeliness of device approvals, timeliness must not come at the cost of safety.

I understand that FDA is required to do much with limited resources. Because it does not receive adequate resources from Congress, the user fee program continues to increase as a percentage of FDA’s resources. From Fiscal Year 2003 to 2008, MDUFMA funding has increased at a much faster rate (220.1 percent) than FDA’s program level device review budget (31.3 percent). As a result, FDA becomes increasingly more dependent on the very industry it was created to regulate.

We must ensure that adequate enforcement tools, resources, and processes are in place to ensure that devices are safe and effective. When I supported the Medical Device User Fee and Modernization Act in 2002, I envisioned this program providing a down payment on an increased level of post-market surveillance. The current reauthorization provides us with a process to increase safety and compliance activity. FDA on its own has taken some steps to increase post-market safety, such as its “Post-market Transformation Initiative.” We now have an opportunity to explore other ways to enhance safety.

We recognize that we must act fairly quickly to prevent a possible exodus of qualified staff and other experienced medical officers at FDA whose positions are funded by user fees. We ran into an unusual situation in 2005 when uncertainty as to whether corrective legislation would be enacted before the October 1, 2005, appropriations “trigger” date, required FDA to impose a hiring freeze in its Center for Devices and Radiological Health. In response to this problem, we passed the Medical Device User Fee Stabilization Act of 2005.

I appreciate the importance of this hearing. I look forward to the testimony of witnesses and the input of our Members as we discuss the MDUFMA reauthorization.

Prepared by the Committee on Energy and Commerce

2125 Rayburn House Office Building, Washington, DC 20515